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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,677	07/07/2003	Geng Zhang	279.609US1	6323

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EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,677	ZHANG ET AL.	
	Examiner	Art Unit	
	Alyssa M Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4, 6, 9-11, 14, 16, 19-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ripart (US 6,385,485). Ripart discloses a device for continuously monitoring cardiac events in an active implantable medical device. The implantable medical device can be a pacemaker, defibrillator and/or cardiovertor, "that detects and automatically indicates a situation establishing the death of the patient, and freezes the last acquired recordings of the cardiac information, namely the heartbeat rate data and/or event markers, for the purpose of later analysis"(col. 2, lines 6-10). The examiner considered the microprocessor to be the controller.

As to claims 4 and 14, "this device is preferably characterized in that the inhibiting circuit means detects a spontaneous and/or electrostimulated cardiac activity, and a parameter indicative of a patient's metabolic demand, these two types of detection being advantageously combined so as to operate the inhibiting circuit means to stop the recording only in the event of the detection of an absence of cardiac activity parameter, confirmed by an absence of a parameter indicative of a patient's metabolic demand. The patient's metabolic demand parameter is preferably one or both of a

patient physical activity parameter and a patient physiological parameter corresponding to patient effort"(col. 2, lines 23-34).

As to claims 6 and 16, the examiner considers a pacing artifact to be a result of pacing the heart, which can be seen on an EKG signal. Therefore, if a pacing pulse was administered, then there would be a pacing artifact. Since a pacing pulse is administered when there is no intrinsic beats, and an evoke response is the result of a capture, if there was no capture then there would be no evoked response. Furthermore, if no intrinsic beats and no evoked response were detected, then there would inherently only be a pacing artifact.

As to claims 9 and 19, since Ripart discloses in column 2, lines 64-67, "this circuit describes means making it possible to know if, in the event of stimulation, this stimulation was effective, by the detection of a post-stimulation "capture" signal emitted by the myocardium". When an evoked response is not detected as a result of the pacing pulses, the Ripart device then senses a parameter from one or both of the sensors. If there is an absence of activity or effort, then the patient is considered dead. Therefore, the pacing ceases after the failed capture and the sensor(s) confirms the patient's death.

As to claims 10 and 20, figure 1 displays a telemetry connection 2, which makes it "possible to transmit, e.g., by means of a radio frequency telemetry connection 2, the information stored in these memories 3 to an external system, such as a programmer, for an analysis"(col. 3, lines 55-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 2, 5, 7-8, 12, 15, 17-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ripart (US 6,385,485). Ripart discloses the claimed invention except for the sensing of transthoracic impedance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor(s) as taught by Ripart with a transthoracic impedance sensor since it was known in the art that transthoracic impedance measurements can be used to adjust cardiac pacing rate.

As to claims 5 and 15, since Ripart discloses the use of an activity sensor, which is obviously be capable of detecting if there was an increase in activity prior to the detection of patient death, which occurs when there is no physiological response, in this case sensed activity, intrinsic beats and no evoked response is detected.

As to claims 7-8 and 17-18, since Ripart discloses the use of an implantable defibrillator, the defibrillation would obviously be capable of detecting if there was an atrial or ventricular episode prior to the detection of patient death, which occurs when there is no intrinsic beats and no evoked response is detected.

As to claim 22, Ripart discloses that "the present invention can be incorporated in an existing implant such as a pacemaker, a defibrillator and/or a cardiovertor controlled

by software, the particular functions of the invention being put in effect by suitable programming or reprogramming of this software (e.g., downloading by telemetry to the implanted device memory 6 a software routine for performing the stated functions)"(col. 2, lines 50-57). Since the implantable device can be programmed and reprogrammed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing parameters to include the ceasing of pacing since it is well known in the art that external programmers or programming means modify pacing parameters.

2. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ripart (US 6,385,485) in further view of Lekholm (US 4,763,646). Ripart discloses the claimed invention except for the detection of heart sounds. Lekholm teaches that it is known to use an accelerometer to measure heart sounds as set forth in column 1, lines 32-34. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detection of physiological signals as taught by Ripart with the detection of heart sounds as taught by Lekholm, in order to utilize an accelerometer to determine cardiac wellbeing.

3. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ripart (US 6,385,485) in further view of Zhu et al. (US 20030220582 A1). Ripart discloses the claimed invention except for the alarm. Zhu et al. teaches that it is known to use an alarm system as set forth on page 2, paragraph 10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the external monitor as taught by Ripart with the external monitor and alarm as taught by

Zhu et al., in order to notify medical personal by means of the alarm, that a patient is in need of medical attention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Freeberg (US Patent Publication 20040122331 A1) discloses a method of determining and documenting cessation of life using evoked response.

2. Snell (US 5,518,001) discloses a cardiac device with patient triggered storages of physiological sensor data.

3. Langer et al. (US 4,223,678) discloses arrhythmia recorder for use with an implantable defibrillator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter
Examiner
Art Unit 3762

JEFFREY R. JASTRZAB
PRIMARY EXAMINER

5/11/5